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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/566,331   | 02/14/2007  | Michael Lewis        | 04520/048002            | 4211             |
| 78859 7590 03/29/2010 Clark & Elbing LLP / Eisai  EXAMINER |             |                      |                         | INER             |
| 101 Federal Street   |             |                      | SAMALA, JAGADISHWAR RAO |                  |
| Suite 1500<br>Boston, MA 02                                | 110         |                      | ART UNIT                | PAPER NUMBER     |
|  |             |                      | 1618                    |                  |
|  |             |                      |                         |                  |
|  |             |                      | MAIL DATE               | DELIVERY MODE    |
|  |             |                      | 03/29/2010              | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.   | Applicant(s)     |        |  |  |  |
|--|---|------------------|--------|--|--|--|
| Office Action Comments   | 10/566,331  | LEWIS ET AL.     |        |  |  |  |
| Office Action Summary  | Examiner  | Art Unit         |        |  |  |  |
|  | JAGADISHWAR R. SAMALA   | 1618             |        |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c  | orrespondence ac | ldress |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                  |        |  |  |  |
| Status   |   |                  |        |  |  |  |
| <u>_</u>   |   |                  |        |  |  |  |
| 1) Responsive to communication(s) filed on   |   |                  |        |  |  |  |
| <i>;</i> —   | <del>-</del>  |                  |        |  |  |  |
| ,  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |                  |        |  |  |  |
| closed in accordance with the practice under E   | x parte Quayle, 1955 C.D. 11, 45  | 03 O.G. 213.     |        |  |  |  |
| Disposition of Claims  |   |                  |        |  |  |  |
| 4)⊠ Claim(s) <u>1-18</u> is/are pending in the application.  |   |                  |        |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |                  |        |  |  |  |
| 5) Claim(s) is/are allowed.  |   |                  |        |  |  |  |
| 6) Claim(s) is/are rejected.   |   |                  |        |  |  |  |
| 7) Claim(s) is/are objected to.  |   |                  |        |  |  |  |
| 8) Claim(s) 1-18 are subject to restriction and/or   | election requirement.   |                  |        |  |  |  |
| Application Dances   |   |                  |        |  |  |  |
| Application Papers   |   |                  |        |  |  |  |
| 9)☐ The specification is objected to by the Examiner.  |   |                  |        |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.  |   |                  |        |  |  |  |
| Applicant may not request that any objection to the  |   |                  |        |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |                  |        |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                  |        |  |  |  |
| Priority under 35 U.S.C. § 119   |   |                  |        |  |  |  |
| 12)☐ Acknowledgment is made of a claim for foreign   | priority under 35 U.S.C. § 119(a)   | -(d) or (f).     |        |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   |   |                  |        |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |                  |        |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |   |                  |        |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |   |                  |        |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |                  |        |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |                  |        |  |  |  |
| •  |   |                  |        |  |  |  |
|  |   |                  |        |  |  |  |
| Attachment(s)  | , <b>.</b>  | (DTG 4:5)        |        |  |  |  |
| Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 4)  |                  |        |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)   | 5) Notice of Informal P   |                  |        |  |  |  |
| Paper No(s)/Mail Date  | 6) 🔲 Other:   |                  |        |  |  |  |

## **DETAILED ACTION**

## Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11, drawn to a method for inhibiting the growth of cells in a blood vessel, said method comprising contacting said cells with a halichondrin analog.

Group II, claim(s) 12-17, drawn to a stent comprising a halichondrin analog coated on its surface.

Group III, claim(s) 18, drawn to a method for decreasing the risk of restenosis in a coronary artery or a bypass graft of a patient.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The above groups lack a common special technical feature that makes a contribution over the prior art. IS Pat. 6,653,341 disclose the compound of Group I, which appears to be the common technical feature between Groups I-III.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/ Primary Examiner, Art Unit 1618 Jagadishwar R Samala Examiner Art Unit 1618 Application/Control Number: 10/566,331 Page 4

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sjr